

F I P S

November 10, 2003
Section 135/2 Iliinka str.
Moscow 103 735
OOO "Sojuzpatent"

Your ref.: SE 3294. 44 18.08.2003

(21) Our ref.: 2001135819/13/038578

Patent Attorney
A.P. Agoureev
Reg. No. 590

OFFICIAL ACTION

(21) Application No. 2001135819/13 (038578)

(22) Filing date: January 3, 2002

(86) PCT Application JP01/02017

(96) Application. No EA

(71) Applicant(s): JAPAN AS REPRESENTED BY PRESIDENT OF KOBE
UNIVERSITY

(51) IPC G 01 N 21/27, 21/35, 33/04, 33/48

QUESTIONS, ARGUMENTS, REMARKS, SUGGESTIONS

Having considered the Applicant's reply, the Section of the food industry and biotechnology finds as follows:

1. Applicant has amended the claims.

2. However, the Examiner has some remarks to make on the matter concerned:

a) in claim I, as filed, a fourth step of making a diagnosis of mastitis in cows is to decide on a group of known cows, with a SIMCA model available therefor, which an "unknown" cow better corresponds to; however, we are unclear as to a criterion by which the "unknown cow" is referred to either the sick or the healthy. In the reply to the Official action, the Applicant points out to a comparison of the spectral characteristics performed for the "unknown" cow with those plotted for a group of known healthy cows and a group of known mastitis-sick cows (cf. the reply to the April 18, 2003 Official

Action, page I). In the Examiner's view, this statement is an essential feature required for achieving a technical result and, therefore, the Applicant would have to recite it in the claims;

b) Applicant continues by stating that a parameter usable in mastitis diagnosis is normally the number of somatic cells, for example, in raw milk and that in different states this threshold value may vary in accordance with national norms (cf. op. cit.). However, if the criterion in making a diagnosis of mastitis are spectral characteristics being dependent on the number of somatic cells in a test material, then it is necessary to show the approximate spectra in irradiating urine, milk or mammary glands in the healthy cows and in the sick cows. It is also necessary to give an exemplified spectral graph showing the dependence between the number of somatic cells and a spectrum pattern resulting from the irradiation of relevant material. The drawings (Fig 4 and Fig. 5) of the materials, as originally filed with the application, give the spectral diagrams showing the dependence between the optical density of the material tested and a wavelength; however, the need is dictated for data to be given on the specific number of somatic cells corresponding to the specific optical density of the material tested. This must be done for confirmation of conformity of the claimed invention with a condition of patentability "industrial applicability".

c) An illustration of realization of a method is afforded by experimental data, Applicant's, as obtained in measuring IR spectra on a mammary gland of a cow, using the said apparatus Fruit Tester 20.

Applicant also believes that the possibility to give a diagnosis of mastitis according to the method, at least so far as claimed in the application, does not actually require any exemplification. However, under § 3.2.4.5 (4) Rules-I (carried into effect 19. 10. 03) for an invention relating to the method, the examples show a sequence of actions over a material object, conditions for carrying out actions, concrete modes and apparatuses used for the

purpose, if necessary. The Examiner believes that it will be advisable in this particular case if the Applicant cites a concrete example illustrating the use of the method. And it is necessary to show the specific rays applied for irradiation and what was exposed to irradiation: urine, milk or a mammary gland, an intensity of concrete rays detected, the results obtainable in irradiating the cows known to have been sick or healthy beforehand and "unknown" cows, a criterion used in comparing the "unknown" cow and the "known" one; which group were they referred to — the healthy or the sick, i.e. whether the presence of the mastitis was or not diagnosed in them. Absence of the given examples in the specification to the application does not allow one to evaluate the compatibility of the claimed invention with a condition of patentability "industrial applicability". Besides this, all the additional materials, as submitted by the Applicant, should be translated into Russian.

3. Also, as stated by the Applicant himself (the specification, pp. 1-3) the number of somatic cells is an important index for mastitis diagnosis, and mastitis diagnosis methods, based on determination of the number of somatic cells, are well known. For Applicant's information, we say that known from state of the art is a method for diagnosing mastitis, comprising the IR irradiation of raw milk from healthy cows, from sick cows and plotting the reference graphs of transmission coefficient levels, IR irradiation of the raw milk of unknown cows, a comparison of the spectral characteristics of the unknown cows with those of the healthy and sick cows and identification of milk from the healthy or sick cows on the basis of this comparison (of. SU 1832008 A1, 07. 08. 93, 4 sheets). The present method enables one to make a diagnosis of mastitis in animals quickly and in time, at an initial latent stage. Known in the art also is a method of the quantitative determination of particles, the somatic cells included, in milk, urea and other media by irradiating same with IR light with a wavelength of between 300 and 10 000 nm (cf. RU 97118363 A, 27.08. 1999, 3 sheets). The known method also provides the possibility to operatively perform control over a medium

sample without necessarily placing it in an apparatus for analysis.

It is hence only logical to see that for the afore-said distinctive features there has been revealed the prior knowledge thereof and the prior knowledge of an effluence exerted by them on an attainable technical result and, for this very reason, the method, as called for in the claims, does not meet a condition of patentability "inventive height".

4. In view of the foregoing, the Section of the food industry and biotechnology invites the Applicant to analyze the Examiner's arguments, correct the claims and specification and substantiate compliance of the claimed invention with a condition of patentability "inventive height", whereupon examination of the application will be continued.

Chief State Patent Examiner

O.V. Skorodoumova